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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,375	07/07/2000	ANTHONY DAVID ORMEROD	ABLE-0014	4066

7590

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EXAMINER

WILLIAMSON, MICHAEL A

ART UNIT

PAPER NUMBER

1616

10

DATE MAILED: 03/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/530,375

**Applicant(s)**

ORMEROD ET AL.

**Examiner**

Michael A. Williamson

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2001.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 24-26 and 28-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 24-26 and 28-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) ✓
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## **DETAILED ACTION**

### ***Pending Claims***

The pending claims in the instant application are 24-26 and 28-39. The only independent claim is 24.

### ***Claim Rejections - 35 USC § 112***

1. The rejection of claims 24-26 and 28-39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention with regard to the recitation of “pharmacologically active analogue, derivative or pro-drug thereof” not adequately describing the materials used and/or how to make said materials has been withdrawn in view of Applicant’s amendment.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 24, 25, 28, 30-34 and 36-39 are rejected under 35 U.S.C. 102(a) as being anticipated by Jackman et al. (Pub. No.: US 2001/0031769).

Jackman et al. discloses a composition comprising rapamycin (sirolimus) which is both a macrocyclic lactone antibiotic and an immunosuppressive macrolide, an alkanolic acid, an aromatic alcohol, benzyl alcohol, and a thickening agent wherein the composition is used in the treatment of inflammatory and hyperproliferative skin diseases and of cutaneous manifestations of immunologically-mediated diseases which includes psoriasis, Lichen planus, etc. (see Abstract, page 1, paragraph [0001], page 2, paragraphs [0029], [0037] and [0038], page 3, [0058], page 4, paragraphs [0060] through [0078], page 5, paragraphs [0090] and [0092] and claims 1-10).

***Claim Rejections - 35 USC § 103***

4. The rejection of Claims 24-26 and 28-39 under 35 U.S.C. 103(a) as being unpatentable over Gans et al. (U.S. Patent 5,648,389) has been withdrawn in view of Applicant's amendment.

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5. Claims 24-26 and 28-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gans et al. (U.S. Patent 5,648,389) in view of Jackman et al. (Pub. No.: US 2001/0031769).

Gans et al. generically discloses a composition comprising erythromycin and caprylic acid in an amount of 0.1 to 30% by weight (see col. 2, lines 41-57) that may include other therapeutic agents in a dermatologically acceptable carrier (see col. 3, lines 26-45) that is topically applied (see Abstract and col. 2, lines 26-41) that is used in the treatment of dermatological conditions. Gans et al. does not disclose that the instant claimed invention includes an antibiotic selected from the group consisting of sirolimus, FK506 or SDZ ASM 981.

Jackman et al. discloses a composition comprising rapamycin (sirolimus) which is both a macrocyclic lactone antibiotic and an immunosuppressive macrolide, an alkanolic acid, an aromatic alcohol, benzyl alcohol, and a thickening agent wherein the composition is used in the treatment of inflammatory and hyperproliferative skin diseases and of cutaneous manifestations of immunologically-mediated diseases which includes psoriasis, Lichen planus, etc. (see Abstract, page 1, paragraph [0001], page 2, paragraphs [0029], [0037] and [0038], page 3, [0058], page 4, paragraphs [0060] through [0078], page 5, paragraphs [0090] and [0092] and claims 1-10). The

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advantage of the composition taught by Jackman et al. is that it treats similar as well as different diseases therefore enhancing the properties of the composition taught by Gans et al. Therefore it would have been obvious to one of ordinary skill in the art to use the materials taught by Jackman et al. in the invention of Gans et al. to obtain a composition that is functionally equivalent as well as an enhancement with undue experimentation since the materials are functionally equivalent in the absence of a factual showing to the contrary or a showing of unexpected results.

### *Response to Arguments*

6. Applicant's arguments with respect to claims 24-26 and 28-39 have been considered but are moot in view of the new ground(s) of rejection.

### *Conclusion*

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within

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TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8.

**Crystal Mall 1 Facsimile Center**

A facsimile center has been established in Crystal Mall 1, room 7C10. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is (703) 308-4556. The new location should be used in all instances when faxing any correspondence to Group 1600. Use of the new Crystal Mall 1 center will facilitate rapid delivery of materials to the Group. The faxing of all papers must conform with the notice published in the Official Gazette, 1096 O.G. 30 (November 15, 1989).

9. Any inquiry concerning this communication or earlier communication from the examiner should be directed to Michael A. Williamson whose telephone number is (703) 308-1235.



Michael A. Williamson  
Patent Examiner  
Group 1610

Williamson020228  
February 28, 2002